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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,356	09/20/2003	Craig A. Rosen	PS904	4830
22195	7590	09/19/2006		
HUMAN GENOME SCIENCES INC. INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850				
			EXAMINER ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/664,356

Applicant(s)

ROSEN ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11,12,16,20,21,24-29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) 20,21,24 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11,12,16 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's response to the Office Action mailed May 5, 2006 on August 7, 2006 is acknowledged. Applicant's comments regarding a rejoinder following notification of an allowable product is noted.

### ***Claim Disposition***

2. Claims 11-12, 16, 20-21, 24-29 and 31-33 are pending. Claims 11-12, 16 and 25-29 are under examination. Claims 20-21, 24 and 31-33 are withdrawn from prosecution as directed to a non-elected invention, however, the status of the claims is "Previously Presented", which should be changed to "Withdrawn".

### ***Maintained-Specification Objection***

3. The specification remains objected to because of the following informalities:

The specification remains objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TAQMAN®, AMPLITAQ GOLD®, for example, have been noted in this application (see page 33). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in

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any manner, which might adversely affect their validity as trademarks. As the specification is large, applicant is urged to review it for other occurrences.

Correction is required.

#### ***New-Claim Objection***

4. Claims 11 and 25 are objected to because of the following informalities:

Claims 11 and 25 are objected to for the recitation of "amino acids 1-419 and 20-419 of SEQ ID NO:1562" because SEQ ID NO: 1562 has 414 residues as set forth in the sequence listing filed on September 20, 2003, this is viewed as typographical error.

Correction is required.

#### ***Withdrawn-Priority Objection***

5. Previous objection to priority documents with regard to disclosure of the polypeptide structure claimed in the instant application is withdrawn by virtue of applicant's arguments presented on pages 11-12 of the amendment. Based on the voluminous amount of priority documents clarification is sought as to what date the instant claimed sequence gets benefit to. It is noted that the ADS filed has 34 pages of priority documents listed.

#### ***Withdrawn-Claim Objections***

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6. Previous objection to the claims is withdrawn by virtue of amendments submitted.

***Withdrawn-Compliance Objection***

7. The instant application complies with the sequence rules with the submission of the required statement.

***Withdrawn-Claim Rejections - 35 USC, 101***

8. Previous rejection to claims under 35 U.S.C. 101, with regard to non-statutory subject matter, is withdrawn by virtue of submission of an amendment.

***Withdrawn-Claim Rejections - 35 USC, 101/112***

9. Previous rejections to claims under 35 U.S.C. 101, with regard to utility; and 112 first paragraph with regard to not being supported by a specific utility and insufficient deposit material are withdrawn by virtue of submission of an amendment and arguments presented on pages 16-17.

***Withdrawn-Claim Rejections - 35 USC, 112***

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10. Previous rejection to claims under 35 U.S.C. 112, second paragraph, is withdrawn by virtue of submission of an amendment.

***Withdrawn-Claim Rejections - 35 USC 102***

11. Previous rejection to claims under 35 U.S.C. 102, is withdrawn by virtue of applicant's arguments presented on pages 18-19.

***Maintained and Amended-Claim Rejections - 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 11-12, 16 and 25-29 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protein contained in SEQ ID NO:1562, does not reasonably provide enablement for any fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to

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support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

Undue experimentation is required to practice the claimed invention because the claims encompass an unspecified amount of fragments that are not supported by the instant specification. The claimed invention is directed to an isolated polypeptide comprising a first amino acid sequence at least 95% identical to a second amino acid sequence such as "a fragment of at least 30 contiguous amino acid of SEQ ID NO:1562 or at least 50 contiguous amino acids of SEQ ID NO:1562", wherein said fragment regulates the production and/or secretion of IL-8. The claims are directed to any contiguous stretch of 30 or any 50 amino acid residues in the 414 residues contained in SEQ ID NO:1562, and said residues are described as regulating the production and/or secretion of IL-8. The instant specification does not provide any empirical evidence of any 30 residues for example, having the recited function. On page 23 of the specification it is disclosed that the invention relates to human secreted proteins/polypeptides, useful for detecting, preventing, diagnosing, prognosticating, treating and/or ameliorating cancer and other hyperproliferative disorders. No real association is made between the activity claimed and the claimed product. For example,

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the specification does not provide any showing of the claimed polypeptide fragments in an assay producing the effect of regulating the production of IL-8 or the secretion of IL-8. It is noted that page 3410 (Table 1D) discloses that "assays measuring production of IL-8 are well known in the art and may be used or routinely modified to assess the ability of polypeptides of the invention (including antibodies and agonists or antagonists of the invention) to regulate production and/or secretion of IL-8". However, none is exemplified in the instant specification with the claimed polypeptide or fragments of at least 30 or at least 50 contiguous residues of SEQ ID NO:1562. A search of the claimed sequence produced a reference that teaches a protein that is 100% identical to the claimed sequence (SEQ ID NO:1562), however, said sequence is used for treating pathologies relating to reproductive abnormalities, involving spermatogenesis and endocrinological defects (see U.S. Patent No. 6,600,019 and the alignment), which does not substantiate the claimed activity.

The claims do not require, any conserved regions or identify any active sites. Due to the large quantity of experimentation necessary to generate the infinite number of fragments recited in the claims and possibly screen same for specific activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation.

Predictability of which potential changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of



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modification and which are conserved (for example, expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, for example, multiple substitutions. In this case, the necessary guidance has not been provided in the specification. Therefore, while it is known in the art that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited, as certain positions in the sequence are critical to the protein's structure/function relationship. It is also known in the art that a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many cases. For example, various sites or regions directly involved in binding activity and in providing the correct three-dimensional spatial orientation of binding and active sites can be affected (see Wells, *Biochemistry*, vol. 29, pages 8509-8517, 1990). The skilled artisan would recognize the high degree of unpredictability that all the fragments encompassed in the claims would retain function. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in

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the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The state of the prior art provides evidence for the high degree of unpredictability as stated above. Seffernick et al. (J. Bacteriology, vol. 183, pages 2405-2410, 2001) disclose two polypeptides having 98% sequence identity and 99% sequence identity, differing at only 9 out of 475 amino acids (page 2407, right column, middle and page 2408, Fig. 3). The polypeptides of Seffernick et al. are identical along relatively long stretches of their respective sequences (page 2408, Fig. 3), however, these polypeptides exhibit distinct functions. The modifications exemplified in the Seffernick et al. reference is small compared to those contemplated and encompassed by the claimed invention. In addition, Guo et al. (PNAS, vol. 101, no.25, pages 9205-9210, 2004) disclose that a third of single amino acid changes would completely inactivate the average protein and the more substitutions made the more probability that the protein will be inactivated. Thus, this gives the sense of what one of skill in the art can expect when a claim embraces fragments with up to 10, 20, 30, 40 or more amino acid changes and how many mutants one of skill in the art can test in such an endeavor. Note that the claims broadly recite at least 30 or at least 50 amino acids, thus no limit on the size of the fragment or how much variability will occur in the protein claimed.

The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. Furthermore, while recombinant and mutagenesis techniques are known in the art, it is not routine in

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the art to screen large numbers of mutated proteins where the expectation of obtaining similar activity is unpredictable based on the instant disclosure. The amino acid sequence of a protein determines its structural and functional properties, and predictability of what mutations can be tolerated in a protein's sequence and result in certain activity, which is very complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's function from mere sequence data are limited, therefore, the general knowledge and skill in the art is not sufficient, thus the specification needs to provide an enabling disclosure.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed fragment. The nature and properties of this claim is difficult to ascertain from the examples provided, as one of skill in the art would have to engage in undue experimentation to construct the fragments of the claimed invention and examine the same for function.

The specification does not provide support for the broad scope of the claims, which encompass an unspecified amount of fragments. The claims broadly read on any fragment thereof for the given sequence (SEQ ID NO: 1562). The issue in this case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary

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skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test fragments of the claimed invention would constitute undue experimentation. Making and testing the infinite number of possible fragments to find one that function is undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

13. Claims 11-12, 16 and 25-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a polypeptide that comprises a first amino acid sequence at least 95% identical to a second amino acid sequence selected from

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for example a full length polypeptide of SEQ ID NO: 1562 or polypeptide fragment of at least 30 or at least 50 contiguous amino acids etc., (see claim 11). The claims have been amended to recite that said fragments regulates the production and/or secretion of IL-8. The claims encompass a genus of protein fragments not adequately described. No correlation is made between structure and function, thus the specification lacks adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention. A search of the claimed protein produced references that indicate that said structure is a NOVX polypeptide or a polypeptide involved in reproductive disorders, no association was found of the claimed structure with IL-8 as claimed. The instant specification makes mention of an assay in general terms, however, no description is provided of the instant polypeptide and fragments of at least 30 or 50 residues in association with the recited activity.

Additionally, the instant specification has not provided a representative number of species for the claimed genus. A representative number of species means that the species, which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

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Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The claimed genus of polypeptides could include non-functional proteins or proteins with a different function than the one described. Therefore, the genus of claimed polypeptides encompasses widely variant species. Based on the unlimited variations contemplated one skilled in the art would at best expect a protein that is different or at worst a protein that is not functional.

*Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

### ***Response to Arguments***

14. The Amendment filed on August 7, 2006 has been considered. The objection of the specification regarding trademarks remain because Applicant on page 11 of the response state that an amendment will be submitted once the pending claims are deemed allowable. Note that the rejection under 35 U.S.C. 101, utility has been withdrawn, thus applicants comments on pages 14-16 and the Exhibits have been considered, however, are moot. Applicant's comments regarding other rejections of record, now withdrawn will not be addressed herein. The rejections under 35 U.S.C. 112, first paragraphs remain, however have been amended to reflect amendments made to the claims. Note also that a new objection has been instituted for the reasons stated above.

The enablement rejection of record is discussed on pages 16-17. Applicant state that claims 11 and 25 have been amended to recite "contiguous" and "regulates the production and or secretion of IL-8"; and have cancelled claims 13, 17 and 30, thereby obviating or rendering moot all the examiner's rejections. Note that portions of the rejection of record has been withdrawn such as the deposit information rejection and the rejection pertaining to utility. The amendments made to the claims and the arguments presented were insufficient to obviate portions of the rejection pertaining to the claimed

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genus of polypeptide fragments and the recited function. The claimed invention as amended does not provide adequate support for the recited function in association with the enormous amounts of fragments encompassed in the claims. The claims are drawn to any 30 or 50 contiguous residues in the 414 residues contained in SEQ ID NO:1562 and no evidence is provided of said fragments having the asserted function. The issue at hand is the invitation to make and test the claimed fragments. A skilled artisan would have to first construct all the fragments encompassed in the claims and then test the same for the recited function as no guidance/direction is given as to conserved regions or active sites. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Thus, the rejection remains.

With regard to the written description rejection, portions of the rejection pertaining to deposited material has been withdrawn. Applicant on pages 17-18 state that claims 11 and 25 have been amended to recite "contiguous" and "regulates the production and/or secretion of IL-8". It is further stated that claims 13, 17 and 30 have been cancelled, thus the rejection should be withdrawn. The amendments made do not obviate the rejection of record because the amended claims remain problematic with regard to containing a large variable genus of protein fragments not adequately described. It is noted that the claims now recite at least 30 or 50 contiguous amino acid residues in the claimed sequence, however, this means any 30 contiguous stretch of



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amino acids in the 414 residues contained in SEQ ID NO:1562. The instant specification does not describe any region of the sequence that needs to be conserved or identify active sites. The specification does not provide a representative amount of species to demonstrate possession of the claimed genus. Furthermore, the instant specification does not provide adequate written description with regard to the claimed fragments retaining the activity as claimed. There is no showing in the specification of an assay wherein the claimed protein fragment regulated IL-8 production with regard to either inhibition or activation of IL-8 production or secretion. There is no showing in the specification that the over production of the claimed protein fragments has a direct association with up or down regulation of IL-8 production or secretion. The instant claims read on a fragment that is 30% or 31% or 32% or 40% or 41% for example having the recited function. Note that U.S. Patent No. 6,600,019 provides a sequence that is 100% identical to SEQ ID NO:1562, however, said sequence is used for treating pathologies relating to reproductive abnormalities, involving spermatogenesis and endocrinological defect, which does not substantiate the claimed activity (alignment attached again for ease). Furthermore, said fragments may not retain the purported activity or may be non-functional or have a different function as set forth in the aforementioned patent. The assertion of a function does not endow said function and the instant application is devoid of exemplification to describe such a claim. Thus, the claimed invention lacks adequate written description and the rejection remains.

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RESULT 2  
 US-09-755-665-55  
 ; Sequence 55, Application US/09755665  
 ; Patent No. 6600019  
 ; GENERAL INFORMATION:  
 ; APPLICANT: Prayaga, Sudhirdas K.  
 ; APPLICANT: Majumder, Kumud  
 ; APPLICANT: Taillon, Bruce B.  
 ; APPLICANT: Spaderna, Steven K.  
 ; APPLICANT: Spytek, Kimberly A.  
 ; APPLICANT: MacDougall, John  
 ; TITLE OF INVENTION: NOVEL POLYPEPTIDES AND NUCLEIC ACIDS ENCODING SAME  
 ; FILE REFERENCE: 15966-631  
 ; CURRENT APPLICATION NUMBER: US/09/755,665  
 ; CURRENT FILING DATE: 2001-08-14  
 ; PRIOR APPLICATION NUMBER: U.S.S.N. 60/174,724  
 ; PRIOR FILING DATE: 2000-01-06  
 ; NUMBER OF SEQ ID NOS: 118  
 ; SOFTWARE: PatentIn Ver. 2.1  
 ; SEQ ID NO 55  
 ; LENGTH: 414  
 ; TYPE: PRT  
 ; ORGANISM: Homo sapiens  
 US-09-755-665-55

NOVEL  
 polypeptides  
 & DNA

Query Match 100.0%; Score 2130; DB 2; Length 414;  
 Best Local Similarity 100.0%; Pred. No. 1.7e-197;  
 Matches 414; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1	MNPTLGLAIFLAVLLTVKGLLKPSFSPRNYKALSEVQGWKQMAAKELARQNNDLGPKLL	60
Db	1	MNPTLGLAIFLAVLLTVKGLLKPSFSPRNYKALSEVQGWKQMAAKELARQNNDLGPKLL	60
Qy	61	KKLAFYNPGRNIFLSPLSISTAPSMCLGAQDSTLDEIKQGFNFRKMPKDLHEGPHYII	120
Db	61	KKLAFYNPGRNIFLSPLSISTAPSMCLGAQDSTLDEIKQGFNFRKMPKDLHEGPHYII	120
Qy	121	HELTQKTQDLKLSIGNTLFIDQRLQPKFLEDAKNFYSAETILTNPQLEMAQKQINDP	180
Db	121	HELTQKTQDLKLSIGNTLFIDQRLQPKFLEDAKNFYSAETILTNPQLEMAQKQINDP	180
Qy	181	ISQKTHGKINNLIENIDPGTVMLLANYIFFRARWKHEFDPNVTKEEDPFLEKNSSVKVPM	240
Db	181	ISQKTHGKINNLIENIDPGTVMLLANYIFFRARWKHEFDPNVTKEEDPFLEKNSSVKVPM	240
Qy	241	MFRSGIYQVGYDDKLSCTILEIPYQKNITAIPILPDEGKLKHLEKGLQVDTFSRWKTLLS	300
Db	241	MFRSGIYQVGYDDKLSCTILEIPYQKNITAIPILPDEGKLKHLEKGLQVDTFSRWKTLLS	300
Qy	301	RRVVDVSVPRLLMTGTFDLKKTLGYIGVSKI FEEHGDLTKIAPHRSKLVGEAVHKAEKLM	360
Db	301	RRVVDVSVPRLLMTGTFDLKKTLGYIGVSKI FEEHGDLTKIAPHRSKLVGEAVHKAEKLM	360
Qy	361	DERGTEGAAGTGAOTLPMETPLVVKIDKPYLLLIYSEKIPSVLPLGKIVNPIGK	414
Db	361	DERGTEGAAGTGAOTLPMETPLVVKIDKPYLLLIYSEKIPSVLPLGKIVNPIGK	414

### Conclusion

15. No claims are allowable.

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16. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner

9/12/06

**HOPE ROBINSON**  
**PATENT EXAMINER**